

# INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

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Frank O'Bannon Governor

Lori F. Kaplan

May 2, 2001

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# EXHIBIT 2

Don Murry
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Re. 097-12128

Permit Amendment to CP 097-3344-00072

Dear Don Murry:

Eli Lilly and Company was issued a permit on July 27, 1994 for research and development facilities. A letter requesting an amendment to the site specific RACT plan was received on March 30, 2000. Pursuant to IC13-15-7-1, this permit is hereby amended as follows:

The page 1 of the Construction Permit CP 097-3341-00072 contains following description of the permitted equipment, which is amended by this letter:

Eli Lilly and Company

is hereby authorized to construct

two pilot plant modules E and F, and portable equipment associated with the pilot plant. Furthermore, pursuant to 326 IAC 8-1-5, this construction permit will authorize Eli Lilly and Company to comply with 326 IAC 8-5-3 through alternative control requirements on the new and existing equipment in the pilot plant in Building 110.

Further, page 1 through 8 of the permit contains a list of equipment at this source.

The existing operation conditions that require amendment are as follows:

- That pursuant to 326 IAC 8-1-5 and 326 IAC 8-5-3 the following shall be met:
  - a) volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to 19.01 tons/year based on a twelve month average rolled on a monthly basis.
  - b) volatile organic compound (VOC) emissions from each facility covered under 326 IAC 8-1-5 shall be limited to 15 pounds per day/33 pounds per day based on calendar month average.

For purposes of determining compliance with the daily emission limit for each facility, Lilly may calculate emissions using the following methods:



- 1. Using monthly mass balance data for each module to prorate a portion of the total emissions from the module to each facility.
- 2. Calculating emissions from solvent and waste solvent storage tanks using equations in section 4.3 of AP-42.
- 3. When a portable emitting facility operates independently of any stationary emitting facility and vents emissions separately from any stationary emitting facility, then the emissions from that portable facility shall be attributed to that portable facility. When a portable emitting facility is connected to and operates in conjunction with any stationary emitting facility and the emissions from portable facility are vented with the emissions from the stationary facility, the emissions from the portable facility shall be attributed to the stationary facility.
- c) the primary reactor condensers will operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature will be 10 degrees C or colder for mixtures that will not freeze at 10 degrees C (includes most non-aqueous streams).
- d) the working fluid temperature at the inlet and outlet of the condensers shall be recorded while condensers are in operation.
- e) any startup, shutdown, or malfunction period causing excessive emissions shall be recorded. The records shall include the start time, end time, and the estimated quantity of excess emissions emitted during the occurrence.
- That a log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 24 month period and made available upon request to the Office of Air Management. A quarterly summary shall be submitted to:

Environmental Resources Management Division Air Pollution Control Section Enforcement Branch, Enforcement Manager 2700 South Belmont Avenue Indianapolis, Indiana 46221

within 60 days after the end of the quarter. The volatile organic compounds (VOC) emissions shall be reported in the format attached.

The page 1 of the Construction Permit CP 097-3341-00072, description of the permitted equipment is modified as follows:

Eli Lilly and Company

is hereby authorized to construct

two pilot plant modules E and F, and portable equipment associated with the pilot plant for "Research and Development activities". Furthermore, pursuant to 326 IAC 8-1-5, this construction permit will authorize Eli Lilly and Company to comply with 326 IAC 8-5-3 through alternative control requirements on the new and existing equipment in the pilot plant in Building 110.

The equipment list on page 1 through 8 of the permit is deleted and replaced by following description:

"Research and Development activities" are activities conducted under close supervision or technically trained personnel that are not engaged in the manufacture of products for sale, exchange for commercial profit, or distribution, except in a de minims manner and the primary purpose of which is to:

- (i) test more efficient production process;
- (ii) test methods for preventing or reducing adverse environmental impacts; or
- (iii) conduct research and development into new processes and products.

Support activities necessary to the research and development activities are considered to be part of the research and development activities. Support activities do not include the provision of power to research and development activities from sources that provide power to multiple projects or from sources that would otherwise require permitting, such as boilers that provide power to a source of solid waste disposal units, such as incinerator.

The amended operation conditions are as follows:

- 4. That pursuant to 326 IAC 8-1-5 and 326 IAC 8-5-3 the following shall be met
  - a) the volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to less than 10 tons per 12 consecutive months period rolled on monthly basis;
  - b) the primary reactor condensers shall operate during reactor venting, material transfer, distillation, and storage of filtrates in reactors, which are transferred from the filters. The primary reactor condensers working fluid inlet temperature shall be 10 degrees C or colder for mixtures that will not freeze at 10 degrees C (includes most non-aqueous streams); and
  - c) the applicant shall submit a quarterly certification that the condensers were operating at all times as required by the condition 4.b. If exceptions to this occur, note the exception, indicate what caused the exception, and how it was corrected.
  - d) the emission units, which have potential to emit VOC greater than 15 pounds per day shall comply with requirements of 326 IAC 8-5-3 (b)(3) through (6) in addition to the site-specific RACT plan requirements.
- A log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Quality. The certification that the condensers were operating at all times shall be submitted quarterly to the following address:

Environmental Resources Management Division Air Pollution Control Section 2700 South Belmont Avenue Indianapolis, Indiana 46221

within 60 days after the end of the quarter. Additionally, an annual summary of volatile organic compounds (VOC) emissions shall also be submitted to above address. The VOC emissions shall be reported within 60 days after the end of the calendar year in the format attached.

The Quarterly Solvent Usage Report on page 12 of 13 of the original permit is replaced with a new form that is attached to this letter. The old reporting form is shown on page 5 of 6 of this letter and new form is shown on page 6 of 6 of this letter. The Quarterly Solvent Usage Report on page 13 of 13 of the permit is deleted because this limit is removed from the permit.

All other conditions of the permit shall remain unchanged and in effect. Please attach a copy of this amendment to the front of the original permit.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter, please contact Gurinder Saini, at (800) 451-6027, press 0 and ask for Gurinder Saini or extension 3-0203, or dial (317) 233-0203.

Paul Dubenetzky, Chief Permits Branch

Office of Air Quality

GS

File - Marion County U.S. EPA, Region V cc:

Marion County Health Department Environmental Resources Management Division - Indianapolis

Air Compliance Section Inspector – Dick Sekula Compliance Data Section - Karen Nowak

Administrative and Development - Janet Mobley

Technical Support and Modeling - Michele Boner

# Indiana Department of Environmental Management Office of Air Quality

Indianapolis Environmental Resource Management Division

Technical Support Document (TSD) for an Amendment to a Construction

Permit

#### Source Background and Description

Source Name: Source Location:

Ell Lilly & Company - Lilly Technology Center 1555 South Harding Street Indianapolis IN 46221

County:

Marion 2834

Permit No.:

097-3341-00072°

**Operation Permit Issuance Date:** 

July 27, 1994

Amendment No.: Permit Reviewer:

097-12128-00072 Gurinder Sain

The Office of Air Quality (OAQ) has reviewed an amendment application from Eli Lilly & Company – Lilly Technology Center relating to the operation of research and development facilities.

#### **Explanation of Modification**

The Permittee has requested to make the following changes to their Construction Permit:

- Replace the equipment list on page 1 through 8 of the Permit with the general description of the "Research and Development activities" under the Part 70 operating permit rule.
- 2. Modify the limit for the Volatile Organic Compounds (VOC) emissions from this Source to 10 tons per year from 19 tons per year.
- Remove 15 lb/day and 33 lb/day VOC emission limit and the associated record keeping and reporting requirements from each facility at this Source.
- 4. The requirement to keep the records of temperature at the inlet and outlet of the condensers to be replaced with a Quarterly Certification that the Condensers were operating at all times.
- Condition regarding reporting malfunction, startup and shutdown to be incorporated in the Quarterly Certification above.
- Modify reporting forms accordingly.

Subsequent to this request, the Permittee revisited the Reasonably Available Control Technology (RACT) determination for this source, which was prepared in 1993. The Permittee evaluated if there were any new development or advances in the control technology for this type of operation. It was determined that there was no change in the technical feasibility determination for different technologies. The economic feasibility of the controls have further decreased because the annual emissions would be reduced by half after this amendment (from 19.6 tons to 10 tons per year).

In the 1993 petition, both absorption/scrubbing and condensation were considered technically feasible options for Building 110. The cost-effectiveness of these two technologies was evaluated in detail in 1993 and found to be economically infeasible.

From the 1993 petition, the overall cost effectiveness for absorption/scrubbing to meet the Rule 8-

5-3 requirements was \$47,110 per ton of VOC removed. Likewise, the overall cost-effectiveness of condensation to meet Rule 8-5-3 requirements was \$34,113 per ton of VOC removed.

Due to further reduction in the limit of VOC emission from this Source by half, the cost effectiveness for absorption/scrubbing to meet Rule 8-5-3 requirements would be \$94,220 per ton of VOC removed. The cost-effectiveness of condensation to meet Rule 8-5-3 requirements would be \$68,226 per ton of VOC removed. These costs are economically infeasible. Therefore, the RACT determination made in 1993 is still valid and there is no revision necessary to the RACT plan.

#### Recommendation

The staff recommends to the Commissioner that the Amendment to the Construction Permit be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on April 04, 2000. Additional information was received on February 14, 2001.

#### Conclusion

This permit amendment shall be subject to the conditions of the attached construction permit amendment letter 097-12128-00072.

# Indiana Department of Environmental Management Office of Air Quality

Addendum to the Technical Support Document for an Amendment to a Construction Permit

#### Source Background and Description

Source Name: Source Location:

1555 South Harding Street Indianapolis IN 46221 Marion

County:

2834

Permit No.:

097-3344-00072

Eli Lilly & Company - Lilly Technology Center

Operation Permit Issuance Date: Amendment No.:

July 27, 1994 097-12128-00072

Permit Reviewer:

Gurinder Saini

On February 26, 2001, the Office of Air Quality (OAQ) had a notice published in the Indianapolis Star, Indianapolis, Indiana, stating that Eli Lilly & Company had applied for an amendment to their Construction Permit for Lilly Technology Center building B110 relating to the operation of research and development facilities.

The notice also stated that OAQ proposed to issue a permit amendment for this operation and provided information on how the public could review the proposed permit and other documentation. The notice informed interested parties that there was a period of thirty (30) days to provide comments on this permit as proposed. Finally, the notice informed the interested parties that a public hearing would be held related to this permit amendment on April 04, 2001 at 7:00 PM at the Marion County Central Library 40 E. St. Clair, Cropsay Auditorium, Indianapolis, IN 46204.

The public hearing was organized at the above mentioned venue at the designated time and date by this office. No comments were received during this public hearing on this matter and no members of public participated in this public hearing.

During the comment period written comments were received from the Permittee related to this permit amendment. These comments and the OAQ response to these comments and any permit changes required are shown in the following paragraphs (bolded language has been added, the language with strikeout has been deleted):

#### Comment 1:

The Permittee has stated that a specific condition be added to the amendment letter to clarify that equipment operating in building B110, including equipment added after the effective date of the permit is subject to the requirements of site-specific Reasonably Achievable Control Technology (PACT) plan as per 326 IAC 8-1-5 instead of 326 IAC 8-5-3 (b)(1) and (2) as determined in the construction permit.

The primary activity at the building B110 involves Research and Development (R and D) for manufacture of pharmaceutical products. Equipment which has the potential to emit greater than 15 pounds per day of VOC, and is used in the manufacture of pharmaceutical products is subject to the provisions 326 IAC 8-5-3.

As the new equipment is added to B 110 for R and D, the Permittee is required to either comply with provisions of 326 IAC 8-5-3 or submit a permit revision request. This permit revision request is to make the site specific RACT requirements in the Construction Permit 097-3341-00072 applicable to the newly added equipment.

The site-specific RACT requirements specified in CP 097-3341-00072 issued on July 27, 1997, allow the alternative control and monitoring requirements in lieu of 326 IAC 8-5-3 (b) (1) and (2) for equipment involved in manufacture of pharmaceutical products.

To reduce the number of revision requests and streamline the process of addition of R and D equipment, the Permittee is seeking that an advanced determination be made in this regard. The Permittee is requesting to add the language in the amendment letter which makes site-specific RACT requirements (in lieu of 326 IAC 8-5-3 (b) (1) and (2)) applicable to any new equipment added to the B 110 which has potential to emit VOC greater than 15 pounds per day and is used to manufacture pharmaceutical products.

#### Response 1:

On the page 2 of 6 of the amendment letter, the OAQ, IDEM has removed the equipment list from the construction permit and replaced it with Research and Development (R and D) activities as single process being carried out at the Building B110. The Permittee had requested to further lower the VOC emissions limit from this process to less than 10 tons per year from the original 19.01 tons per year in the construction permit. This revised emission level from this process and the designation as R and D are insignificant activities. Therefore, the new equipment added to Building B110 does not require any revision to the construction permit, if:

- it is part of this R and D process;
- complies with the site-specific RACT plan requirements specified in the construction permit; and
- the source-wide emissions of VOC are still limited to less than 10 tons per year after the modification.

No change is made to the permit amendment letter.

#### Comment 2:

The Permittee has requested that a specific condition be added to the permit clarifying that the permitted equipment must comply with 326 IAC 8-5-3 (b) (3) through (6). The site-specific RACT plan provides alternate controls and monitoring methods for 326 IAC 8-5-2 (b) (1) and (2) only. The equipment which has potential to emit greater than 15 pounds per day of VOC still needs to comply with 326 IAC 8-5-3 (b) (3) through (6).

#### Response 2:

The OAQ, IDEM has decided to make this change. A new condition (d) is added to the amended condition 4 on the page 3 of 6 of the letter as follows:

d) the emission units, which have potential to emit VOC greater than 15 pounds per day shall comply with requirements of 326 IAC 8-5-3 (b)(3) through (6) in addition to the site-specific RACT plan requirements.

#### Comment 3:

The amended condition 4.a) on page 3 of 6 of the amendment letter limits the VOC emissions from the pilot plant in Building 110 to 0.834 tons per month. The Permittee has stated that this monthly limit is overly restrictive and inconsistent with the permitting practice. The Permittee has requested for a VOC emission limit of 10 tons per year, which should be rolled on a monthly basis.

#### Response 3:

The OAQ, IDEM has decided to make this change. The amended condition 4.a) on page 3 of 6 of the amendment letter is modified as follows:

 the volatile organic compound (VOC) emissions from pilot plant in Building 110 shall be limited to 0.834 tons per month less than 10 tons per 12 consecutive months period rolled on monthly basis;

#### Comment 4:

The Permittee has stated that amended condition 4.c) on page 3 of 6 of the amendment letter implies that condensers are required to operate at all times. However condition 4.b) states when the condensers should be operated. Therefore, it should be stated in condition 4.c) that the condenser were operating as required by condition 4.b).

#### Response 4:

The OAQ, IDEM has made this change as follows:

a) the applicant shall submit a quarterly certification that the condensers were operating at all times as required by the condition 4.b the time. If exceptions to this occur, note the exception, indicate what caused the exception, and how it was corrected.

#### Comment 5:

The amended condition 5 on page 3 of 6 of the amendment letter does not specify time-frame for submitting annual summary of VOC emissions. Permittee is requesting to add a time-frame of 60 days after the end of the calender year to submit annual summary of VOC emissions.

#### Response 5:

The OAQ, IDEM has decided to make a change in the address for submitting reports in addition to the change mentioned in the above comment. The amended condition 5 is modified as follows:

5. A log of information necessary to document compliance with condition no.4, shall be maintained. These records shall be kept for at least the past 36 month period and made available upon request to the Office of Air Quality. The certification that the condensers were operating at all times shall be submitted quarterly to the following address:

Environmental Resources Management Division Air Pollution Control Section Enforcement Branch, Enforcement Manager

# 2700 South Belmont Avenue Indianapolis, Indiana 46221

within 60 days after the end of the quarter. Additionally, an annual summary of volatile organic compounds (VOC) emissions shall also be submitted to above address. The VOC emissions shall be reported within 60 days after the end of the calender year in the format attached.

#### Comment 6:

The VOC reporting form on page 6 of 6 of the amendment letter needs to be modified to show limit of VOC emission based on 12 month rolling average.

#### Response 6:

The reporting form is modified as shown on the next page:

#### Indianapolis Air Pollution Control Section Annual VOC Emissions Report

Eli Lilly and Company Indianapolis, Indiana Pollutant: VOC

Facility I.D.:

**B110 Pilot Plant** 

Construction Permit No.:

CP 097-3341

Plt ID No.: Limit (tons per 12 month period rolled on monthly basis):

097-00072

10 tons

Limit (tons per month)

0.834 tons

# Monthly Emission Data

Year:

Month	Tons VO© emitted this Month*	Tons VOC Emitted in Last 12 Months
December (previous year)		
January		
February		
March		
April		
May	s the state of the supplement of the said	Al
June		
July		
August		
September		
October		
November		

Submitted By: Date Submitted:

Production records that show compliance with this emission limit will be maintained on site and will be made available upon request.

#### Comment 7:

The Permittee has requested to modify the VOC emission reporting form on page 6 of 6 of the amendment letter. This is to be modified to show months from January through December as per the proposed rule 326 IAC 2-6 for Marion County.

#### Response 7:

The change requested by Permittee is based on a proposed rule and can only be implemented when the rule is in force. Therefore, there is no change to the permit amendment.

#### Comment 8:

The Permittee has requested that the construction conditions 1 through 6 and operation conditions 1 through 3 of CP 097-3341-00072 should be deleted from the permit.

The Permittee has argued as follows:

"These conditions are obsolete, extraneous, or environmentally insignificant. The US EPA white paper on implementation of the Part 70 Operating Permit program suggests that NSR permit conditions which are obsolete, extraneous, environmentally insignificant or otherwise not required by the Clean Air Act, and which should not be incorporated into the Part 70 Operating Permit, are ripe for "purging" from the original preconstruction permit. (The conditions should be purged from the preconstruction permit because EPA considers preconstruction permits as having no expiration. This the terms apply until they are amended or deleted through an NSR modification.) If the terms are not purged, they must be incorporated into the Part 70 Operating Permit. Purging the obsolete, extraneous, or environmentally insignificant NSR terms as part of this amendment process will make the Part 70 Operating Permit issuance process easier."

Further in this request Permittee has described in detail the reason why these conditions should be deleted from their permit as also described in their Part 70 Operating Permit Application.

#### Response 8:

The OAQ, IDEM does not agree with the company's recommendation for removing these conditions. The issue of removing conditions that are obsolete, extraneous, or environmentally insignificant will be handled during the Part 70 Operating Permit review process. The OAQ, IDEM has as a policy decided that it will not modify the permits to remove the construction conditions after the construction has been completed by the Permittee. No change is made to the permit amendment.

#### Comment 9:

The Permittee has requested that the first paragraph of the amendment letter should refer to March 30, 2000 as the date when the request for amendment was made.

#### Response 9:

The first paragraph of the amendment letter on page 1 of 6 is modified as follows:

Eli Lilly and Company was issued a permit on July 27, 1994 for research and development facilities. A letter requesting an amendment to the site specific RACT plan was received on April 04 March 30, 2000.

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Eli-Lilly and Company Indianapolis

CP 097-3341 Ph D 097-00072 Review Engineer T.P.Sinha

Indianapolis Air Pollution Control Section
Quarterly Solvent Usage Report

Eli Lilly and Company Indianapolis, Indiana Pollutanta:VOC Facility I.D.: Pilot Plant Construction Permit No.: 097-3341 Plt ID No.: 097-00072

Limit (tons per 12 month period) :19.01 tons

Monthly Emissions Da			
<u>Month</u>	No. of Batches Processed	Tons of VOC Emitted this Month*	Tons of VOC Emitted in Last 12 Months
		-	
Production records report.	which complies with this en	nission limits should be recorde	ed and submitted with
		Submitted By:	- The second
		Date Submitted	

#### Indianapolis Air Pollution Control Section Annual VOC Emissions Report

Eli Lilly and Company Indianapolis, Indiana Pollutant: VOC

Facility I.D.: Construction Permit No.:

B110 Pilot Plant

CP 097-3341 097-00072

vz:141

Plt ID No .: Limit (tons per 12 month period rolled on monthly basis):

10 tons

Month	Tons VOC emitted this Month*	Tons VOC
	ennued uns Monun	Emitted in Last 12 Month
December (previous year)		
January		
February		
March		
April		
May	<u> </u>	
June		
July		
August		
September		As.
October		
November		
oduction records that show comp	liance with this emission limit	will be maintained on site and
de available upon request.		

# Indiana Department of Environmental Management Office of Air Management

# Technical Support Document Addendum for New Construction and Operation

Eli Lilly and Company Indianapolis, Indiana

The office of Air Management has reviewed an application from Eli Lilly and Company relating to the construction and operation of the process equipment for its pilot plant in Building 110 at the Lilly Technology Center-South in Indianapolis. Also, Eli Lilly and Company has petitioned for an alternate site-specific Reasonably available Control Technology (RACT) plan as provided in rule 326 IAC 8-1-5 for reactors, centrifuges, filters and vacuum dryers in Building 110 in lieu of RACT for these equipment specified in rule The 30-day Public Notice was published in The Indianapolis Star on March 8, 1994 and a public hearing was held on March 26, 1994. During the public notice period for the proposed construction permit, Eli Lilly and Company had the following comments. The following are Eli Lilly's comments and

# 1. Eli Lilly's Comments:

In the general description of the permit on page 1 of the draft construction permit Lilly offers the following language to clarify the scope and purpose of the construction permit:

"... is hereby authorized to construct two pilot plant modules E and F and portable equipment associated with the pilot plant. Furthermore, pursuant to 326 IAC 8-1-5, this construction permit will authorize Eli Lilly and Company to comply with 326 IAC 8-5-3 through alternative RACT control requirements on the new and existing equipment in the pilot plant in Building 110.

#### 1. Staff's Response:

IDEM accepts the change in the construction permit language as proposed by Eli Lilly and Company. The construction permit has been changed

#### Lilly's Comments :

Lilly offers the following corrections to the new and existing equipment lists appearing on pages 1 through 5 of the proposed construction permit.

- (a) On page 3, in the equipment list for the new equipment in the Building 110 expansion, the size of the four 14 single plate filters should be changed to 16 inches. This change will not effect the emission estimates for
- (b) The list of new equipment should be expanded by adding the Unit 93 Syltherm Cooling system to the list for C-Wing. Although technically a VOC, Syltherm is a synthetic heating/cooling fluid which has a very low vapor pressure at normal operating temperatures. Consequently, the additional VOC emissions from the Unit 93 Syltherm Cooling system are expected to be very

CP 097-3341 Plt.ID 097-00072 Review Engineer: T.P.Sinha

small (i.e., less than 1 lb/day). An estimate of the emissions will be included as part of the quarterly emissions reports.

- (c) Included in these comments as Attachment A is a list of small, portable pieces of equipment in the existing part of Building 110 that were inadvertently omitted from the equipment description in the petition for a Site-Specific RACT Plan. For the most part, these facilities are small tanks ranging in size from 5 gallons to 75 gallons. Because they are portables, the tanks can be used in any of the modules. Generally they are operated in conjunction with permanent equipment in the modules and the emissions from this equipment are vented through the permanent equipment's vent lines. emissions estimates for the permanent equipment in the existing modules provided in the petition for the Site-specific RACT Plan and the construction permit included the emissions from the portable equipment when it is operated in conjunction with the permanent equipment. This portable equipment is operated on its own much less often than with the permanent equipment. Because of its size and low utilization without permanent equipment, this equipment by itself does not contribute significantly to the emissions from Building 110. Although unlikely to actually emit 15 lb/day., this equipment has the potential to emit more than 15 pounds in any one day, and therefore, is subject to the requirements of 326 IAC 8-5-3. Since the equipment generally emits through existing reactors in the permanent modules, the emissions will be controlled by the primary condensers operating with a working fluid inlet temperature of at least -10 degrees centigrade. Lilly will still be able to comply with the proposed VOC emission limit using this equipment. Emissions from this equipment will be included as part of the quarterly emissions report.
- (d) Included in these comments as Attachment B is a list of 32 walk-in exhaust hoods in which some operations, such as opening a filter to remove the filter cake, are conducted. These hoods are "production equipment exhaust systems" with the potential to emit 15 lb/day, and therefore, are subjects to the requirements of 326 IAC 8-5-3. In the cover letter to the petition for the Site-Specific RACT Plan (dated December 9, 1993) and in Lilly's written response to your request for additional information (dated December 23, 1993(, Lilly explained that although these exhaust systems may emit greater than 33 pounds in one day, it is not cost effective to install emission control equipment to ensure emissions will always be less than 33 lb/day as required by 326 IAC 8-5-3(b)(2). In the aforementioned documents Lilly requested the Commissioner wave the 33 lb/day limit as provided by 326 IAC 8-5-3(b)(2). In order to make the waiver federally enforceable, Lilly requests that IDEM include the waiver in the proposed construction permit.

#### 2. Staff's Response:

- (a) 14 inch single plate filters has been changed to 16 inches.
- (b) Unit 93 Syltherm Cooling system will be added to the equipment list for C-wing. 0.18 tons per year VOC emissions will be added to the total uncontrolled and controlled emissions.

CP 097-3341 Plt.ID 097-00072 Review Engineer: T.P.Sinha

- (c) 66 small portable pieces of equipment have been added to the existing list of equipment. No additional emissions will be emitted from these equipment.
- (d) The emissions from these hoods are as a result of operating filters and centrifuges. These emissions are identified with the source of emissions, in this case filters and centrifuges. The walk-in hoods will be included in the list of existing equipment list. IDEM does not associate any emissions to a facility which is not capable of generating any emissions.

#### 3. Lilly's Comments:

Construction condition 5 on page 6 of the draft construction permit adds unnecessary delay and process to start-up of the newly constructed areas in Building 110. Because the operating permit will be issued by the City of Indianapolis Air Pollution Control Section (IAPCS), Lilly proposes using the procedures in IAPCS permits for obtaining operating permits. The construction permit issued by the IAPCS on July 16, 1993 serves as a temporary operating permit (see condition 1 of construction permit 9300072-01 and Indianapolis Air Control Board Regulation IX-1 Section C.6(a)(i). The permit allows Lilly to begin operation of the newly constructed facilities provided Lilly notifies after actual start-up. Indianapolis Air Control Board Regulation IX-1 Section C.6(a)(i) then requires a source to submit an operating permit application 180 days after start-up. The process used by IAPCS can legally apply to this permit because the operating permit will be issued under the jurisdiction of Condition 5 as follows:

"Pursuant to Indianapolis Air Pollution Control Board Regulation IX-1, this Construction Permit shall serve as a temporary operating permit until such time as a valid operating permit is either issued or denied by the Indianapolis Air Pollution Section (IAPCS), provided:

- a) The permittee submits written notification to the IAPCS of the anticipated initial start-up date of the new facilities not more than sixty nor less than thirty days prior to such date;
- b) The permittee submits written notification to the IAPCS of the actual initial start-up date of the new facilities within fifteen days after such date: and
- c) The permittee submits an application for an operating permit to the IAPCS within 180 days after operation of all the new facilities constructed under this permit.

The operation permit issued by the IAPCS shall contain as minimum the conditions in the Operation Conditions of this

CP 097-3341 Plt.ID 097-00072 Review Engineer: T.P.Sinha

#### 3. Staff's Response:

The construction condition 5 has been revised accordingly.

#### 4. Lilly's Comments:

Lilly requests that the VOC emission limit established in operation condition 4.a) be increased from 18.6 to 18.9 ton/yr. As described below, the increase is necessary to accommodate corrected emissions from the 4000 gallon acetone storage tank and emissions from the 7500 gallon waste solvent storage tank that were omitted from the original submittals. Both tanks will comply with the applicable requirements of 326 IAC 8-5-3.

Lilly recalculated the emissions from the acetone storage tank issuing the equations found in section 3.4 of AP-42. In addition, the annual throughput of acetone in the tank was increased from 14,700 gallons to 26,600 gallons. Therefore, the potential uncontrolled VOC emissions from this tank should be 0.144 ton/yr (0.081 ton/yr working losses + 0.063 ton/yr breathing losses) instead of the 0.03 ton/yr estimated in earlier submittals.

This existing tank will be controlled during tank car deliveries by using a vapor balance system that is at least 90 % efficient in controlling working loss VOC emissions. Consequently, potential controlled working losses will be 0.008 ton/yr. Furthermore, the tank is equipped with a conservation vent valve which should significantly reduce breathing losses. Unfortunately, conservation vent valve. Therefore, the control efficiency from the conservation vent valve is ignored and the breathing losses are assumed to be uncontrolled. Therefore, potential controlled VOC emissions from the acetone storage tank are 0.071 ton/yr (0.008 ton/yr +0.063 ton/y

The emissions from the existing 7500 gallon waste solvent tank were not included in the construction permit application and petition. This tank is equipped with a conservation vent valve to reduce breathing losses. (As with acctone storage tank, the control effectiveness of the conservation vent valve is ignored.) With a potential throughput of 98,400 gallons of waste solvent (approximately 45 % water and 55 % VOC solvent), potential uncontrolled and potential controlled VOC emissions from the tank are 0.169 ton/yr (0.114 ton/yr working losses + 0.055 ton/yr breathing losses).

#### 4. Staff's Response:

Additional emissions of 0.24 ton/yr from acetone and waste tanks, due to the increased throughput and revised calculations, have been added to the proposed VOC emission limit. In addition 0.18 tons per year of VOC emissions VOC emission will also be added to the proposed VOC emission limit. From 18.6 to 19.02 ton/yr

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#### 5. Lilly's Comments :

Page 10 of the Technical Support Document discusses a limit of 80 batches per year on the pilot plant operations in Building 110 as a means to limit potential emissions from Building 110. The permit does not contain any limits on the number of batches. Before discussing the value of including a limit on the number of batches in the pilot plant, Lilly would like to offer some corrections and suggestions.

First, 80 batches was lilly's statistical estimate of the maximum number of batches likely to be processed in any one module, not the entire pilot plant. The emission estimates included in the petition for the Site-Specific RACT Plan and the construction permit application are based on 80 batches per module. There is enough equipment in the Building 110 pilot plant to constitute 15 modules (six large modules A through F, 30 gallon module A, 30 gallon Module B, the dry product containment area, and six possible module configurations in C-wing). Therefore, the maximum number of batches Lilly would anticipate in the Building 110 pilot plant operations is 1200 batches per year (80 batches/yr/module x 15 modules). (Two small laboratory operations in Building 110, the high pressure hydrogenation area and the EML area contain very small-scale type equipment and are considered laboratory research areas and not part of the Building 110 pilot plant. The lab equipment in these areas have extremely small emissions and therefore, are not included within the scope of this permit. "Batches" run in these two areas are not included in

Second, Lilly would like to clarify that one "batch" includes equipment preparation, the chemical reaction process/unit operations and equipment clean-up. All three activities must occur to run a batch and each activity may emit VOCs.

Third, the pilot plant operations must be extremely flexible because of the wide variety of products tested in the pilot plant and because of the experimental nature of testing different chemical processes for one product. The number of batches in a module may vary greatly over the course of a year Therefore, limits on the number of batches which can be run in any one month, will severely limit the usefulness of the pilot plant. No one module should be limit on the number of batches it can process in one year. Likewise, if a limit on production in the permit is required, an annual limit on the number of batches for the entire Building 110 pilot plant provides an acceptable amount of flexibility.

If IDEM believes a limit on production is necessary, Lilly proposes to add the following language at the end of operation condition 4.a):

"Pilot plant operations in Building 110 shall be limited to 1200 batches per year based on a twelve month average rolled on a monthly basis. A batch shall be comprised of equipment preparation activities, the chemical reaction process and associated unit operations, and equipment clean-up."

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#### 5. Staff's Response:

IDEM has corrected the 80 batches per year to 80 batches per module per year. IDEM is not concerned about the number of batches processed, rather its interest lies in the emissions of VOC. Since VOC emissions from the covered faculties will be limited, so the overall production is also limited.

#### 6. Lilly's Comments :

In operation condition 4.b) Lilly suggests changing the averaging period from "30 days" to "monthly". It is simpler for an operating area to evaluate emission rates on a monthly basis, regardless of whether the month contains 28, 30 or 31 days. Therefore, the averaging period for the 15 lb/day limit should be monthly rather than 30 days.

#### 6. Staff's Response:

In operation condition 4.b) the averaging period has been changed from 30 days to monthly.

#### 7. Lilly's Comments :

Lilly appreciates IDEM's inclusion of the language in the second paragraph of operation condition 4.b) to explain how Lilly will determine compliance with the 15 lb/day average VOC limit. For the most part we will be determining compliance with the emissions limit using mass balance data. For some equipment, such as the acetone storage tank and the waste solvent tank, it makes more sense to calculate the emissions using AP-42 emission factors and equations. Therefore, Lilly recommends amending the second paragraph of operation condition 4.b) as follows:

"For purposes of determining compliance with the daily emission limit for each facility, the permittee may calculate emissions using any one or a combination of the following methods:

- 1) Using monthly mass balance data for each module to prorate a portion of the total emissions from the module to each facility.
- Calculating emissions from solvent and waste solvent storage tanks using equations in section 4.3 of AP-42".

### 7. Staff's Response:

IDEM concurs with Lilly and the second paragraph of the operation condition 4.b of the proposed permit has been changed accordingly.

### 8. Lilly's Comments :

Lilly suggests adding a third paragraph to operation condition 4.b) to clarify how emissions from portable equipment will be treated. Portable equipment is capable of being used in many configurations. More often than not, the portable will operate in conjunction with stationary equipment and any emissions from the portable equipment will be vented through the stationary equipment vent line. Occasionally portable equipment will be operated independently with its own venting system. When the portable

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equipment is being operating in conjunction with stationary equipment, it is impossible to distinguish between the emissions from the portable equipment and the stationary equipment. This will make demonstrating compliance with the proposed 15 lb/day average VOC emissions limit extremely difficult. Lilly proposes borrowing language from the construction permit issued by IAPCS to address this issue. The following language should be added as a third paragraph to operation condition 4.b):

"When a portable emitting facility operates independently of any stationary emitting facility and vents emissions separately from any stationary emitting facility, then the emissions from that portable facility shall be attributed to that portable facility. When a portable emitting facility is connected to and operates in conjunction with any stationary emitting facility and the emissions from portable facility are vented with the emissions from the stationary facility, the emissions from the portable facility shall be attributed to the stationary facility."

### 8. Staff's Response:

IDEM concurs with Lilly and a third paragraph has been added to the operation condition 4.b of the proposed permit.

#### 9. Lilly's Comments :

Lilly recommends using consistent terminology in operation condition 4.b) when referring to equipment and facilities. Lilly suggests that instead of "each equipment" that the permit use the terms "each facility".

#### 9. Staff's Response:

The proposed permit has been changed accordingly.

#### 10. Lilly's Comments :

Operation conditions 4.c) and 4.d) establish the operating and record keeping requirements for the "condensers" that comprise the VOC emission reduction strategy for the pilot plant. Lilly requests that the permit conditions refer to these condensers as "primary reactor condensers" to clarify which condensers must be operated in compliance with the permit conditions. The Building 110 pilot plant has some equipment which have a coldwater condenser. These condensers, as described in the petition for a Site-Specific RACT Plan, will reduce some VOC emissions, but are primarily used in order to collect experimental data. The suggested clarification will ensure that the cold-water condensers are not required to be operated as air pollution control equipment and are not required to operate at -10 degrees C.

#### 10. Staff's Response:

The "condensers" in the proposed permit has been changed to "primary reactor condensers" in operation conditions (4)c and (4)d.

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#### 11. Lilly's Comments :

Lilly requests that the requirement to submit a quarterly report to the IAPCS within 30 days after the end of each quarter be extended to 60 days. The actual emission calculations for Building 110 will be done on a monthly basis. Because of the many processes run in the pilot plant and because the emission rates will be based on a mass balance calculation involving many data points for each of the processes run, it takes longer to calculate emission rates from Building 110 than from other Lilly operations which ordinarily rely on less-time consuming theoretical equations. The construction permit issued by quarter.

#### 11. Staff's Response:

Requirement to submit the quarterly report within 30 days, has been changed to 60 days.

#### 12. Lilly's Comments :

Lilly recommends a different quarterly report to show compliance with the 15 lb/day permit limit for each piece of equipment rather than the one proposed on page 9 of the permit. The suggested report is included as Attachment C. (The report format on page 8 of the permit for showing compliance with the annual emission limit is acceptable.)

#### 12. Staff's Response:

Attachment C is accepted as the quarterly report form.

#### 13. Lilly's Comments :

The fourth paragraph on page 2 of the Technical Support Document states that the operations in Building 110 are exempt from Subpart VV of the New Sources Performance Standards (NSPS) relating to the Standard Organic Chemical Manufacturing Industry (SOCMI) because of the capacity of the equipment. Building 110 is exempt from Subpart VV because the pharmaceutical research and development activities in Building 110 do not produce any of the chemicals listed in 40 C.F.R.60.489 as intermediates or final products.

#### 13. Staff's Response:

Even if Eli Lilly and company produces the chemicals listed in 40 CFR 60.489, it is exempt from NSPS requirements as the capacities of the equipment are less than the NSPS applicability threshold of 10,000 gallons.

#### 14. Lilly's Comments:

Throughout the Technical Support Document the acetone storage tank is listed as having a capacity of either 4000 gallons or 4,200 gallons. The correct capacity of the tank is 4,000 gallons.

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#### 14. Staff's Response:

The capacity of the tank has been corrected to 4,000 gallons.

#### 15. Lilly's Comments :

The corrections made to the equipment list in the proposed construction permit (See comment #2 above) should also be made to the equipment list on pages 4 through 9 of the Technical Support Document. In addition, the following corrections should be made.

a) Eliminate one of the portable agitated filter/dryers listed on page 9.

- b) On page 9 Plow Blender VBD500 is listed twice-one of the two should be deleted from the list.
- c) The 4,000 gallon acetone tank and the 7,500 gallon waste tank listed as other equipment on page 9 have already been listed in Table 8 on page 7.
- d) The MACE Cooling System listed as other equipment on page 9 has already been listed in Table 11 on page 8.

#### 15. Staff's Response:

Above additions of equipment and corrections in the number of equipment have been done in TSD.

#### 16. Lilly's Comments :

There is an error in Table 15 of page 13 of the Technical Support Document. Table 15, which is derived from Table 7.3 of the Petition for a Site-Specific RACT Plan submitted by Lilly on December 9, 1993, states that controlled emissions from reactors in Module A are 0.66 tons/yr and the VOC removal efficiency in Module A is 71 %. Table 7.3 of the Site-Specific RACT Plan petition correctly states the controlled emissions from Module A reactors (0.52 ton/yr) and the VOC removal efficiency (77%). For purposes of projecting emissions and control efficiencies if the reactors in Building 110 complied fully with the requirements of 326 IAC 8-5-3, Table 15 should have assumed that the 100 gallon high-pressure hydrogenation reactor would also be controlled with -25 degree C condensers.

# 16. Staff's Response:

The TSD has been corrected accordingly.

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CP 097-3341 Plt.ID 097-00072 Review Engineer: T.P.Sinha

# 17. Lilly's Comments :

The second sentence of Note 1 on page 16 of the Technical Support Document should be revised as follows to clarify the assumptions:

"The temperature of the working fluid in the condensers, measured at the inlet of the condenser, is assumed to be -10 degrees centigrade."

# 17. Staff's Response:

The TSD has been revised accordingly.

#### 18. Lilly's Comments :

The first sentence in the first paragraph on page 17 of the Technical Support Document should be revised to clarify that the reason the 100 gallon hydrogenation reactor is not equipped with a primary condenser is because it high pressures, not that it always operates at high pressures.

#### 18. Staff's Response:

TSD has been corrected accordingly.

#### 19. Lilly's Comments :

In the fifth paragraph on page 17 of the Technical Support Document the emission rate for centrifuges/filters is incorrectly stated as 0.40 tons/day. The correct emission rate is 0.40 tons/year.

#### 19. Staff's Response:

The typographical error has been corrected.

#### NOTICE OF 30-DAY PERIOD FOR PUBLIC COMMENT AND PUBLIC HEARING

Preliminary Findings Regarding a Construction Permit Amendment

for Eli Lilly and Company in Marion County

CP 097-3341-00072 Permit Amendment No.: 097-12128

Notice is hereby given that the above-mentioned company, located at 1555 S.Kentucky Avenue, Indianapolis, Indiana, has made application to the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM) for amending their Construction Permit issued on July 27, 1994 for the conditions in Site Specific RACT Plan. This amendment in the permit language would be a state implementation plan revision. There will be no change in the emissions.

A public hearing will be held related to this permit on April 04, 2001 at 7:00 PM. The hearing will be held at the Marion County Central Library, 40 E. St. Clair, Cropsey Auditorium, Indianapolis, IN 46204.

Notice is hereby given that, any interested person may comment on why this proposed permit amendment should or should not be issued, from the date of publication of this notice through April 04, 2001. Appropriate comments should be related to any air quality issues, interpretation of the state and federal rules, calculations made, technical issues, or the effect that the operation of this source would have on any aggrieved individuals. IDEM, OAM does not have jurisdiction in specifying and implementing requirements for zoning, odor or noise. For such issues, please contact your local officials.

A copy of the draft permit amendment is available for examination at the Indianapolis Marion County Public Library, 40 Clair Street, Indianapolis, Indiana, and the Environmental Resource Management Division, Administration Building, 2700 S.Belmont Ave., Indianapolis Indiana. A copy of the draft permit amendment is also available for examination at www.state.in.us/idem/oam/index.html. All statements, along with supporting documentation, should be submitted in writing to the IDEM, OAM, 100 North Senate Avenue, P.O. Box 6015, Indianapolis, Indiana 46206-6015.

Persons not wishing to comment at this time, but wishing to receive notice of future proceedings conducted related to this action, must submit a written request to the OAM, at the above address. All interested parties of record will receive a notice of the decision on this matter and will then have fifteen (15) days after receipt of the Notice of Decision to file a petition for administrative review. Procedures for filing such a petition will be enclosed with the Notice.

Questions should be directed to Gurinder Saini, OAM, 100 North Senate Avenue, P.O. Box 6015, Indianapolis, Indiana, 46206-6015, or call (800) 451-6027, press 0 and ask for Gurinder Saini or extension 3-0203, or dial (317) 233-0203.

Paul Dubenetzky, Chief Permits Branch Office of Air Management

NOTICE OF 30-DAY PERIOD
FOR PUBLIC COMMENT
AND PUBLIC COMMENT
AND PUBLIC HEARING
Preliminary Findings
Regarding a Construction
Permit Amendment
for Eli Lilly and Company
In Marion County
CP 097-334-00072
Permit Amendment
No.: 097-12128
Notice Is hereby given that
the above-mentioned company, located at 1555 K. Kentucky
Avenue, Indianapolis, Indiana,
has made application to the
Indiana Department of Environmental
Anagement (IDEM), Office of Air Management
In the permit be nowned to the conditions
of the permit on April
(A 2001 at 7:00 PM. The hearing will be held at the Marion
County Central Library, 40 E.
St. Clair, Cropsey Auditorium,
Indianapolis, In 46204.
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from the date of publication of
this notice through April 04,
2001. Appropriate comments
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ENVIRONMENTAL MANAGEMENT MARION COUNTY, INDIANA

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# BEFORE THE STATE OF INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

PUBLIC HEARING REGARDING
TECHNICAL SUPPORT DOCUMENT (TSD)
FOR AN AMENDMENT TO A
CONSTRUCTION PERMIT

# ORIGINAL

#### PROCEEDINGS

in the above-captioned matter, before Hearing Officer Donald Poole, taken before me, Lindy L. Meyer, Jr., a Notary Public in and for the State of Indiana, County of Shelby, at the Indianapolis-Marion County Public Library, Cropsey Auditorium, 40 East St. Clair Street, Indianapolis, Indiana, on Wednesday, April 4, 2001 at 7:08 o'clock p.m.

William F. Daniels, RPR/CP CM d/b/a
ACCURATE REPORTING OF INDIANA
12922 Brighton Avenue
Carmel, Indiana 46032
(317) 848-0088

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1	APPEARANCES:
2	ON BEHALF OF THE INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT:
3	
4	Donald Poole, Hearing Officer Gurinder Saini
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7:08 o'clock p.m. April 4, 2001

THE HEARING OFFICER: I'm going to open up the public hearing. My name is Donald Poole. I am an environmental engineer with the Air Permits Branch of the Indiana Department of Environmental Management. I will be conducting this hearing this evening.

This is a hearing for Eli Lilly, an amendment to a construction permit numbered 097-12128. The purpose of this hearing is to address any concerns related to a request by Eli Lilly and Company to make a change to a construction permit which involves a State Implementation Plan, SIP, revision.

Gurinder Saini is here as the permit reviewer. We have a court reporter here to transcribe what goes on at the hearing. This provides us with a transcript to review if we have to address the comments and questions that are raised at this hearing. It will provide a record if anyone's interested in getting a copy of that.

We placed copies of the proposed amendment in the Indianapolis-Marion County Public Library. A public noticed was published in the Indianapolis Star in Indianapolis. This notice was published on February 26th, 2001. There was a 30-day public comment period. We also brought a copy of the permit documents, which anyone can review.

The permit amendment sets out what Eli Lilly and Company intend on doing. Due to the type of request made related to one of the requirements in the State Rule 326 IAC 8-5-3, the change which the company wants to make is viewed as a SIP revision.

Seeing no one, I guess that ends this public hearing.

Thereupon, the proceedings of April 4, 2001 were concluded at 7:10 o'clock p.m.

#### CERTIFICATE

I, Lindy L. Meyer, Jr., the undersigned Court Reporter and Notary Public residing in the City of Shelbyville, Shelby County, Indiana, do hereby certify that the foregoing is a true and correct transcript of the proceedings taken by me on Wednesday, April 4, 2001 in this matter and transcribed by me.

Lindy L Meyer, Jr.,

Notary Public in and for the State of Indiana.

My Commission expires October 27, 2008.